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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES *ex rel.* JAYDEEN VICENTE, STATE OF ILLINOIS *ex rel.* JAYDEEN VICENTE; STATE OF ARKANSAS *ex rel.* JAYDEEN VICENTE; STATE OF CALIFORNIA *ex rel.* JAYDEEN VICENTE; STATE OF DELAWARE *ex rel.* JAYDEEN VICENTE; STATE OF FLORIDA *ex rel.* JAYDEEN VICENTE; STATE OF HAWAII *ex rel.* JAYDEEN VICENTE; STATE OF INDIANA *ex rel.* JAYDEEN VICENTE; STATE OF LOUISIANA *ex rel.* JAYDEEN VICENTE; STATE OF MASSACHUSETTS *ex rel.* JAYDEEN VICENTE; STATE OF MONTANA *ex rel.* JAYDEEN VICENTE; STATE OF MICHIGAN *ex rel.* JAYDEEN VICENTE; STATE OF NEVADA *ex rel.* JAYDEEN VICENTE; STATE OF NEW HAMPSHIRE *ex rel.* JAYDEEN VICENTE; STATE OF NEW YORK *ex rel.* JAYDEEN VICENTE, STATE OF TENNESSEE *ex rel.* JAYDEEN VICENTE; STATE OF TEXAS *ex rel.* JAYDEEN VICENTE; COMMONWEALTH OF VIRGINIA *ex rel.* JAYDEEN VICENTE; DISTRICT OF COLUMBIA *ex rel.* JAYDEEN VICENTE and JAYDEEN VICENTE INDIVIDUALLY, Plaintiffs, v. ELI LILLY AND COMPANY, Defendant.	§	CIVIL ACTION NO. 07 1791 UNDER SEAL

FILED
MAY - 3 2007
MICHAEL E. KUNZ, Clerk
By _____ Dep. Clerk

COMPLAINT

Qui tam Plaintiff/Relator Jaydeen Vicente ("Plaintiff-Relator"), on behalf of the United States of America; the States of Illinois, California, Delaware, Florida, Hawaii, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New York, Tennessee, Texas, Virginia and the District of Columbia (collectively "Plaintiff States") and herself individually, for her Complaint against Defendant Eli Lilly and Company ("Lilly" or "Defendant Lilly") alleges based upon personal knowledge and relevant documents, as follows:

I. NATURE OF ACTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the Plaintiff States (collectively the "Government Plaintiffs") arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendant Lilly and/or its agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 *et seq.*, as amended ("the FCA" or "the Act") and its state-law counterparts: the California False Claims Act, Cal. Govt Code §12650 et sec ; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. §68.081 et se; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 et seq.; the New York False Claims Act, New York State Finance Law, Article 13, §§187 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 et seq.; the

Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 et seq.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§1-1188.13 et seq.

2. The instant matter arises in principal part from Defendant Lilly's nationwide, coordinated deceptive off-label marketing and promotional practices for its potent atypical antipsychotic Zyprexa. Specifically, Lilly devised and successfully implemented through its divisions of Zyprexa sales representatives a marketing campaign calculated to increase physicians' off-label use of Zyprexa, in various doses, to treat symptoms, mood disorders and patients within age demographics for which the drug has not received FDA approval, nor which has been supported by the medical compendia DRUGDEX, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia-Drug Information.

3. The conduct alleged herein shows a pattern of conduct designed to maximize profits at Government Plaintiffs' expense.

4. Lilly's Zyprexa sales representatives were among primary resources used by Lilly to dramatically increase Zyprexa sales for off-label uses to beneficiaries of Government-funded health care plans, including Medicaid, Medicare, Department of Veterans health care benefits programs (the "VA") and the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), now known as TRICARE Management Activity/CHAMPUS ("TRICARE/CHAMPUS").

5. Lilly organized its sales force into several divisions. These divisions included a ***Long Term Care*** ("LTC") sales force, which Lilly paid and gave incentives such as bonus programs to promote Zyprexa use in the elderly demographic. The

Zyprexa LTC sales representatives' sole objective was to promote Zyprexa within the LTC market, *i.e.*, to increase market share and revenues derived from elderly residents of LTC facilities. Lilly provided extensive training, funding and Zyprexa product support (including advertising materials and exaggerated and misleading pro-Zyprexa studies) to its "specialty" LTC sales force tailored to promote the drug to geriatric healthcare providers (closed-end pharmacies, geriatric physicians and LTC facilities) through misleading, deceptive and wanton means. Lilly also paid kickbacks masquerading as speaker fees, honoraria, unrestricted educational grants, entertainment and other in-kind forms that Lilly at all times intended to be payments in exchange for increasing the usage and/or dosage of Zyprexa in elderly LTC facilities. Lilly engaged in this conduct purposefully and foreseeable to increase Zyprexa off-label sales revenues.

6. Lilly's illegal and zealous off-label over promotion of Zyprexa off-label was a calculated campaign to increase sales of Zyprexa in the elderly population for dementia symptoms, agitation, insomnia and many other generic symptoms without regard for the safety of the patients for these untested, unapproved uses.

7. Plaintiff-Relator has personal knowledge that Lilly engaged in the Zyprexa off-label promotional effort in Long Term Care ("LTC") facilities and in primary care physicians' offices in every state in the nation.

8. Lilly's illegal Zyprexa marketing campaign was calculated to, and did, cause billions of dollars of Zyprexa to be prescribed off-label to vulnerable, elderly long term care nursing home residents and adults (who at most were depressed or presented with other mood-related symptoms or illnesses) since the drug was unveiled in 1996. These expensive prescription purchases were funded principally, in whole or in part, by

government-funded healthcare programs including Medicaid, Medicare, the VA and CHAMPUS/Tricare.

9. Lilly succeeded. Lilly's LTC sales force was the most successful of all Lilly's sales teams based upon earnings per salesperson. Specifically, Plaintiff-Relator gained personal knowledge from Lilly corporate employees during Lilly's regional and national sales conferences and from the sales data Lilly made available to her, that the Zyprexa revenues generated per LTC sales representative far exceeded the revenues generated per sales representative in any of its other Zyprexa sales division.

10. The purchases of the billions of dollars of dangerous, potent off label Zyprexa prescriptions were funded in principle part by the Government Plaintiffs by and through the, *inter alia*, Medicaid program. The Government Plaintiffs would not have funded billions of dollars of Zyprexa purchases since the drug's launch in 1996 but for Lilly's unlawful, intentionally deceitful and aggressive marketing tactics alleged herein.

11. Lilly's conduct endangered the health of government program beneficiaries by placing them at great risk of harm of developing serious, irreversible and even life-threatening side effects that were known to Lilly at all times relevant to this Complaint, but which Lilly intentionally concealed to protect its windfall of billions of dollars of annual Zyprexa sales revenues.

12. Hundreds of thousands of Medicare, Medicaid, VA and CHAMPUS/Tricare beneficiaries have now and continue to fall victim to serious, irreversible diseases and or potentially life threatening medical conditions including diabetes and hyperglycemia, in addition to the substantially increased risk of death for some patients, especially the elderly, after commencing Zyprexa drug therapy as a direct

and proximate cause of Lilly's Zyprexa marketing ploy. Lilly knew, or recklessly disregarded, Zyprexa's numerous hazardous side effects. Lilly chose instead to conceal Zyprexa's risks and dangers to reap astronomical profits as a cost of doing business.

13. Lilly owes the federal government and Plaintiff States for prescription costs which were funded through health programs including Medicaid, Medicare, the VA and CHAMPUS/Tricare.

14. Lilly's fraudulent scheme caused substantial consequences for the Government Plaintiffs. The Government Plaintiffs improperly paid tens of millions annually for prescriptions of Zyprexa that were ineligible for reimbursement. Unfortunately, the federal False Claims Act and the analogous laws of the Plaintiff States does not provide for a recovery of the exorbitant costs the Government Plaintiffs are now saddled with funding to treat the diseases and afflictions unwittingly suffered by program beneficiaries because of Zyprexa, which Lilly caused through its unlawful marketing of its blockbuster drug Zyprexa.

15. The FCA and the laws of the Plaintiff States permit any person discovering a fraud perpetrated against the Government to bring an action for herself and for the Government and to share in any recovery. Plaintiff-Relator commences this *qui tam* action individually and on behalf of the Government Plaintiffs to recover treble damages and civil penalties under the Federal False Claims Act §§ 3729-3730 and the analogous laws of the Plaintiff States.

II. PARTIES

16. Plaintiff-Relator brings this action on behalf the Government Plaintiffs to remedy the millions of dollars Medicare, Medicare, the VA and CHAMPUS/Tricare have

been fraudulently induced to pay as a result of false Zyprexa reimbursement claims submitted by, and caused to be submitted by, Defendant Lilly. The Government Plaintiffs and Plaintiff-Relator Vicente will be collectively referred to as "Plaintiffs."

17. Plaintiff-Relator Vicente is a citizen of the United States and resident of the State of California. She resides at 7 Castle Hill Court, Vallejo, CA, 94591. Plaintiff-Relator Vicente was employed by Eli Lilly ("Lilly") for three years beginning in February 2000 as a Long Term Care Pharmaceutical Representative. In this capacity, Lilly trained, paid and directed Plaintiff-Relator to promote Zyprexa off-label to treat elderly LTC skilled nursing facility residents in Northern California. Lilly offered Zyprexa selling incentives to Plaintiff-Relator by structuring a bonus program available to her based upon sales revenues of Zyprexa generated in her territory from LTC sales.

18. Defendant Eli Lilly and Company is an Indiana corporation and has its principle place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. At all times relevant hereto, Lilly was engaged in the business of licensing, manufacturing, distributing, promoting and/or selling, either directly or indirectly, the pharmaceutical prescription drug Zyprexa throughout the United States, through its third party agents and/or employees, including its LTC sales force and its primary care physician sales divisions.

III. FILING UNDER SEAL

19. In accordance with 31 U.S.C. § 3730(b)(2), this complaint is filed *in camera* and will remain under seal and will not be served on the Defendant Lilly until the Court so orders. A copy of the complaint and written disclosure of substantially all material evidence and information the Plaintiff possesses have been served on the United States pursuant to 31 U.S.C. § 3730(b)(2) and FED.R.CIV.P. 4(i).

IV. ORIGINAL SOURCE

20. Through her employment as Lilly "specialty" LTC sales representative trained and employed to promote Zyprexa for off-label uses, specifically, for use in the elderly LTC demographic, as is alleged with particularity *infra*, Plaintiff-Relator acquired a wealth of direct, independent and non-public knowledge of Lilly's unlawful acts described in this Complaint.

21. Plaintiff-Relator gained personal knowledge of Lilly's kickback payments to physicians made for the purpose, and with the intent to, induce those physicians (both geriatric physicians and PCPs) to prescribe Zyprexa to his or her Medicaid beneficiary patients.

22. Plaintiff-Relator has personal knowledge of Lilly's corporate endorsement of this unlawful national off-label Zyprexa marketing scheme for the LTC market as well as other markets including primary care and also has personal knowledge of the specific Lilly corporate personnel responsible for implementing Zyprexa's off-label marketing.

23. Accordingly, Plaintiff-Relator is an "original source" of the non-public information alleged in this Complaint within the meaning of 31 U.S.C. § 3730(e)(4)(A) and (B).

24. Plaintiff-Relator is concurrently providing to the Attorney General of the United States, the United States Attorney for the Eastern District of Pennsylvania a disclosure statement summarizing and supported by known material evidence in accordance with the provisions of 31 U.S.C. §3730(b)(2) and applicable state law.

V. JURISDICTION AND VENUE

25. This Court has jurisdiction over the subject matter of this civil action,

arising under the laws of the United States, pursuant to: (i) 31 U.S.C. §3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730; (ii) 28 U.S.C. §1331, which confers federal subject matter jurisdiction; and (iii) 28 U.S.C. §1345, because the United States is a plaintiff.

26. Jurisdiction over the state law claims alleged herein is proper under 31 U.S.C. §3732(b). This Court has supplemental jurisdiction over all state law claims under 28 U.S.C. §1367.

27. This Court has jurisdiction under 31 U.S.C. §3732(a) over Defendant Lilly because the drug company can be found in, is authorized to transact business in, and is now transacting business in this District.

28. Venue is proper in this District under 31 U.S.C. §3732(a) and 28 U.S.C. §1391.

VI. THE MEDICAID AND MEDICARE PART D PRESCRIPTION DRUG REIMBURSEMENT BENEFIT.

A. The Medicaid Program

29. Title XIX of the Social Security Act is a program that provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children. Among the health benefits funded by Medicaid up until January 1, 2006 was funding for the prescription drug needs of the Program's beneficiaries.

30. At all times relevant to the Complaint, in most states, Medicaid was an

open-ended federal-state matching program. The federal government contributes a fixed percentage of the state's Medicaid costs each year; however, the exact percentage the federal government contributes varies year to year using a formula that takes into account the state's per capita income relative to the national per capita income.

31. The percentage of state contribution the funding of prescription drug purchases, and all other covered Medicaid health benefits, typically amounted to at least 40% at all times relevant to the complaint.

B. The Medicare Part D Program

32. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. The health insurance provided to beneficiaries of the Medicare insurance program is paid in whole or in pat by the United States.

33. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of needy classes of individual healthcare patients pursuant to federal regulation.

34. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare ("Medicare Part D").

35. Medicare Part D went into effect on January 1, 2006. The Program is administered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid ("CMS"). For "dual eligibles," defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for

other health care in 2005, enrollment in Medicare Part D was compulsory. Such beneficiaries were automatically switched to Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

36. The VA and CHAMPUS/Tricare operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

C. Reimbursement Limits on Off-Label Drug Prescriptions

37. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs.

38. The Medicaid program includes individualized provisions, by statute and regulation, concerning reimbursement for prescription drugs, drug utilization review, the eligibility of various drugs for federal financial participation ("FPP"), price controls on prescription drugs and drug manufacturer rebate agreements.

39. According to the Social Security Act, the Plaintiff states are entitled to FFP for reimbursement of pharmacies for covered a patient drugs. 42 U.S.C.A. §1396r-8. The definition of covered outpatient drug is limited to drugs used for medically excepted indications. 42 U.S.C.A. 1396(k)(3). A medically accepted indication is any use approved by the FDA can or supported by any of the three specific compendia. *Id.* (k)(6). The compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information and the Drugdex Information System. *Id.* at (g)(1)(b)(i).

40. By way of example, under the Florida Medicaid Program the determination of whether a drug is eligible for reimbursement and prescribed for a purpose that is covered by Medicaid is governed by 42 U.S.C. 1396r-8, Chapter 465 F.S., and the Florida Medicaid Prescribed Drug Services Provider Handbook.

41. In addition to the statutory authority granted by 42 U.S.C. 1396r-8 allowing state Medicaid programs to exclude or otherwise restrict coverage of outpatient prescription drugs, pursuant to the Florida Medicaid Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook to be reimbursed by Medicaid, a drug must be medically necessary and prescribed for medically accepted indications and dosages found in the **(A)** drug labeling ("labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article), the **(B)** American Hospital Formulary Service Drug Information, the **(C)** United States Pharmacopeia-Drug Information or the **(D)** DRUGDEX Information System.

42. Whether the use of a drug is medically necessary was material Medicaid's decision to reimburse for prescription. Consequently, the government would deny reimbursement for claims made for prescriptions of Zyprexa if it had known the purpose for which the drug had been prescribed was medically unnecessary.

43. Use of Zyprexa, for example, for dementia, or for anxiety or depression in the elderly is not supported by the compendia as medically safe and effective, and therefore should not have been covered by the Government Plaintiffs' Medicaid programs, yet nonetheless, Lilly recklessly has promoted Zyprexa for those and other unauthorized, untested and unproven uses through the methods alleged in this Complaint.

44. Lilly expected and intended its unlawful Zyprexa promotional efforts to cause claims for reimbursement to be submitted to Medicaid programs throughout the country; specifically, Lilly designed and implemented its aggressive promotional tactics to influence the prescribing choices of long-term care and primary care physicians who treat beneficiaries of government-funded healthcare programs. The intended and foreseeable effect Lilly's avaricious scheme was that the Medicaid program would fund the cost of treatment with Zyprexa through its reimbursement claims system and accordingly, that its promotional efforts would directly and substantially increase its Zyprexa revenue stream at *inter alia* Medicaid expense.

45. Until recently, the Government Plaintiffs were unaware of the unlawful manner in which Lilly promoted Zyprexa throughout the United States. Lilly knew or should have known the Medicaid regulations governing prescription drug reimbursement.

46. Under the Federal False Claims Act and the analogous laws of the Plaintiff States, it is unlawful for any "person," as defined by the statute, to submit a false or fraudulent claim to Medicare and Medicaid. The act of submitting a false claim includes by definition causing another to submit a false claim as well as soliciting, receiving, offering or paying any kickback, bribe or rebate in connection with a Medicaid claim.

47. The Federal False Claims Act, and the analogous laws of the Plaintiff States, provide for penalties of up to $11,000.00 for each violation of the foregoing provisions.

48. Lilly has caused false claims to be submitted to Medicaid for reimbursement through its promotional efforts in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States.

49. In summary, throughout the country, Lilly aggressively and intentionally marketed Zyprexa for non-indicated uses and non-medically necessary uses including for the treatment of general mood and behavior disorders, attention deficit disorder, the attention deficit hyperactivity disorder, depression ***not*** associated with psychosis, sleeplessness, autism, Alzheimer's, dementia and aggression and agitation associated with dementia and Alzheimer's. Further, Lilly has intentionally misrepresented to prescribers who treat Medicaid participants that Zyprexa is safer than less expensive, generic antipsychotics such as Haldol which costs pennies per day rather than the extraordinary expense of Zyprexa.

50. By and through this and other conduct, Lilly caused tens of thousands of prescription reimbursement claims for Zyprexa prescribed for medically unnecessary and non-indicated uses to be submitted to the Medicaid/Medicare programs for reimbursement. However, the prescription drug reimbursement claims for off-label uses of Zyprexa Lilly caused to be submitted to the Government as a direct result of its unlawfully off-label promotion campaign were not eligible for reimbursement from Medicaid, the VA or CHAMPUS/Tricare (and Medicare Part D, when it came into effect on January 2006) because such off-label uses were neither listed in the labeling approved by the FDA nor otherwise supported as safe and effective by any of the drug compendia specified by the Medicaid statute.

51. Lilly engaged in its national Zyprexa promotional blitz with the knowledge that the majority of Zyprexa prescriptions written as a result thereof are reimbursed by government-funded health programs such as Medicaid, as well as with the knowledge that such prescriptions were for non-medically accepted indications and non-

medically necessary uses of Zyprexa the fall outside the coverage of Medicaid.

VII. BACKGROUND

A. FDA Regulation of Drug Companies and their Marketing Practices

52. As detailed below, Lilly's conduct also materially and wantonly violated the FDA's regulations and federal law governing off-label marketing and truthful labeling and promotion of prescription drugs. Lilly engaged in this profit-driven misconduct for the purpose of deceiving physicians with their false and fraudulent off-label marketing message to cause the submission of false claims for Zyprexa to the Government Plaintiffs.

1) The FDA's Regulation of Promotional Activities of Drug Manufacturers.

53. A prescription drug's product labeling contains the drug's indication. Drug product labeling broadly defined by federal regulation, including 21 C.F.R. § 202.1(k)(2), which provides that drug manufacturers' marketing and promotional materials for their drugs aimed at physicians, *i.e.*, all brochures, handouts, detail aids, slide shows or other such promotional materials, are also defined as "product labeling" and are stringently regulated as such. By law, representations made in any labeling material must be truthful, not misleading and represent a fair balance of the information presented. Any failure to fairly and accurately represent the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. *See* 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

54. Pharmaceutical promotional materials and presentations lacking in fair balance or that are otherwise false or misleading, violate the Food Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated hereunder. Such violations

exist where promotional and marketing materials and presentations for an FDA approved drugs reference "off-label" uses or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated or are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

55. "Off-label" prescribing of drugs occurs when a drug is used by a medical professional beyond the drug's indication. This includes prescribing a drug for a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or to treat a different patient population (*e.g.* treating a child with the drug when the drug is approved to treat adults).

56. Lilly materially violated these clear-cut labeling and misbranding regulations to illegally increase sales of its blockbuster drug in the off-label elderly market by and through its marketing and promotional efforts of its LTC sales force in direct-to-physician marketing.

57. Lilly, unable to control and bolster Zyprexa revenues by directly submitting prescription drug reimbursement claims to Medicaid and Medicare, instead launched a campaign intended to increase Government-funded off-label purchases of Zyprexa by defraud LTC physicians, pediatric physicians and primary care physicians ("PCPs") to prescribe Zyprexa. The natural, intended and foreseeable effect consequence of such unlawful, premeditated conduct caused physicians and pharmacists to submit claims to publicly-funded health plans that were ineligible for reimbursement pursuant to these programs' regulations.

58. Each such claim Lilly knowingly caused to be submitted under these false pretenses in derogation of the labeling and misbranding laws, and each false statement it made to cause claims to get claims for Zyprexa paid, constitutes a false claim for which Lilly accountable under the Government Plaintiffs' False Claims Acts.

2) Federal Law Prohibits Off-Label Marketing To Protect the Health and Safety of Patients.

59. Off-label marketing by pharmaceutical companies is closely regulated by the FDA and the law because of its inherent dangers. These regulations protect patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an ostensibly independent, scientific governmental body, the FDA.

60. Under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose (notably, however, Lilly's creation of a LTC sales division directly evidences Lilly introduced Zyprexa into interstate commerce with the specific intent that it be used for off-label purposes, *i.e.*, to treat vague cross-over symptoms in the elderly, as pleaded with specificity herein), and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

61. Physicians are not prohibited from prescribing an FDA-approved drug "off-label"; however, pharmaceutical promotional activities and marketing materials and presentations are false or misleading in violation the Food Drug and Cosmetics Act and regulations promulgated hereunder if they advertise "off-label" uses of a drug, or

expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated.

62. When pharmaceutical companies illegally encourage off-label uses for their drugs, the number of prescriptions rises, thereby causing Medicaid and other programs to pay out more for prescriptions that are not eligible for payment. Lilly intended for its "off-label" promotional campaign to improperly increase the submissions of off-label Zyprexa prescriptions, including such prescriptions reimbursed by the Medicare and Medicaid programs.

63. Lilly's off-label marketing programs have been extremely successful, leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

64. Any claim submitted for a drug when the drug was prescribed for an off-label use not only violates Medicare payment rules but also files a fraudulent claim under the False Claims Act. 31 U.S.C §3802. Claims for Zyprexa prescriptions induced to be written and submitted by Medicaid/Medicare participating pharmacy benefits providers to the Government for reimbursement as a direct and foreseeable result of Lilly's illegal off-label marketing campaign has caused the Plaintiff United States and the Plaintiff States to suffer substantial economic harm.

B. Zyprexa's Limited Indicated Uses

65. In September of 1996, the FDA approved Zyprexa tablets for use in the treatment of adults of schizophrenia at target doses of 10mg per day. In 2001, the Zyprexa tablets were approved for treatment of adults suffering from acute manic

episodes associated with biploar I disorder at dosages of up to 20mg per day. In July of 2003, Zyprexa tablets were approved for the short-term treatment of adults suffering from acute manic episodes associated with bipolar I disorder, in combination with lithium or **Depakote (valproic acid)**, with a recommended doses of 10 to 20mg per day. In January of 2004, Zyprexa tablets were approved for long-term treatment of adults diagnosed with bipolar disorder in doses of up to 20mg per day.

66. In 2001, Lilly launched ZYPREXA Zydis, an orally disintegrating tablet form of Zyprexa. ZYPREXA Zydis was specifically identified as an "opportunity" in Lilly's 2001 LTC Business Plan.

67. ZYPREXA Zydis tablets were made available in 4 strengths: 5 mg, 10 mg, 15 mg, and 20 mg. ZYPREXA Zydis has essentially the same efficacy and safety profile as regular ZYPREXA tablets, and is indicated by the FDA for the same conditions: schizophrenia, maintenance of treatment response in schizophrenia and acute mania associated with bipolar I disorder in patients experiencing a manic or mixed episode.

68. The purpose of the introduction of the new disintegrating tablet form of Zyprexa was for "Convenient Administration." Because this Zyprexa tablet is formulated to easily dissolve within seconds of being placed in the patient's mouth, the drug was touted by Lilly as an important additional option for treating elderly patients, who may have difficulty swallowing a regular tablet form. In addition, Lilly promoted Zydis as providing a convenient alternative to liquid formulations of other drugs, and because absorption is not affected by food, it can be taken without regard to meals or drinking liquids, although, if patients wanted to drink something along with the medication, they may, but it is not necessary.

69. Lilly provided Plaintiff-Relator with training materials to assist in the promotion of ZYPREXA Zydis in the LTC demographic.

I. Medical Compendia Limited Supported Uses of Zyprexa

70. The HFS, the United States Pharmacopeia–Drug Information and the DRUGDEX information system support the use of Zyprexa in adult (not geriatric) schizophrenic or bipolar patients **only**. The uses supported by the three compendia and the FDA approved labeling are collectively defined as Zyprexa's "Medically Accepted Indications" in the Federal Medicaid Act, 42 U.S.C.A. § 1396r-8. Neither the compendia cited above nor the FDA-approved labeling supports any use of Zyprexa by the elderly, by children or for treatment of adults with depression, anxiety, ADD, ADHD, sleep disorders, anger management, mood enhancement or mood stabilization.

VIII. PLAINTIFF-RELATOR'S PERSONAL KNOWLEDGE OF LILLY'S SUCCESSFUL, NATIONAL OFF-LABEL ZYPREXA MARKETING AND PROMOTIONAL PRACTICES.

71. In or about February 2001, Lilly hired Plaintiff-Relator as a Long Term Care ("LTC"), Specialty, Pharmaceutical Representative.

72. Plaintiff-Relator's hiring came on the heels of one of Lilly's expansions of its LTC sales division. Since Lilly established the LTC sales division, which upon information and belief occurred simultaneously with the drug's launch in 1996, Lilly periodically expanded the LTC sales division.

73. At the time Lilly hired Plaintiff-Relator, there were 160 LTC Zyprexa sales representatives whose territories spanned the United States. See Exhibit "A." Initially, there were only 15 LTC sales representatives. In August 1999 that number was expanded to 59. In March 2000, concomitant with Zyprexa gaining sales momentum in